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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/629,913 | 07/30/2003 | Michael Garabedian | GARABEDIAN=2A | 8615 |
| 1444 | 7590 | 11/09/2004 | EXAMINER | |
| BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303 | | | GAMETT, DANIEL C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 11/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/629,913 | GARABEDIAN ET AL. | |
| | Examiner | Art Unit | |
| | Daniel C Gamett | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, drawn to a molecule comprising the antigen binding portion of an antibody specific for glucocorticoid receptor phosphorylated at residue Ser 211, or at residue Ser 226, classified in class 530, subclass 387.1.
 - II. Claim 4, drawn to a method for determining the presence of activated glucocorticoid receptors in cells obtained from human glucocorticoid responsive tissues, classified in class 435, subclass 7.1.
 - III. Claims 4 and 5, drawn to a method for determining the presence of activated glucocorticoid receptors in cells obtained from human patients treated with a glucocorticoid, classified in class 514, subclass 12.
 - IV. Claims 6, drawn to a method of screening for a glucocorticoid agonist, classified in class 435, subclass 4.
 - V. Claim 7, drawn to a method of isolation of a glucocorticoid agonist, classification dependent upon structure of agonist.
 - VI. Claim 8, drawn to a glucocorticoid agonist, classification dependent upon structure of agonist.
 - VII. Claims 9-11, drawn to a molecule comprising the antigen binding portion of an antibody specific for glucocorticoid receptor phosphorylated at ser 203, classified in class 530, subclass 387.1.

2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody product of Group I, can be used to detect phosphorylated glucocorticoid receptors in settings other than human cells or tissues specified in Groups II-IV. It can be used in non-human animal cells transfected with an expression vector encoding the human glucocorticoid receptor, for example. It can also be used for *in vitro* experiments using purified components designed to identify kinases that are capable of phosphorylating the glucocorticoid receptor at ser 211 or ser 226.
4. Furthermore, searching Group I together with any of II-IV would impose a serious search burden. The inventions of Groups I and II-IV have a separate status in the art as shown by their classifications. Moreover, in the instant case, the search for the antibody product and the methods of determining the presence of activated glucocorticoid receptors and of screening for a glucocorticoid agonist are not co-extensive. For Group I, the high degree of structural conservation of the pertinent domain of the glucocorticoid receptor raises the possibility that the antibodies of claim 1 recognize phosphorylated serine residues in glucocorticoid receptors from

non-human species, thus necessitating an avenue of search that would not be used for Groups II-IV. In contrast, the search for Groups II-IV would require a text search for the steps in the diverse methods in addition to a search for the antibody of Group I. Additionally, even if the antibody product were known, the methods of using the product may not be novel or unobvious in view of the preamble or active steps.

5. The inventions of Groups I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The products of Group I and Group VII are antibody molecules specific for structurally and functionally distinct antigens. As such, the two antibody products are used in different protocols and for different purposes. For these reasons the inventions of Groups I and VII are patentably distinct. Furthermore, because of their divergent antigen specificities, simultaneous examination of the inventions of Groups I and VII would impose a significant search burden.
6. The Inventions of Groups II, III, IV, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that the methods of Groups II, III, IV, and V can be used together. The method for determining the presence of activated glucocorticoid receptors in cells obtained from human glucocorticoid responsive tissues (Group II), the method for determining the presence of activated glucocorticoid receptors in cells obtained from human patients (Group

III) the method of screening for a glucocorticoid agonist (Group IV), and the method for isolating a glucocorticoid agonist (Group V) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Specifically, Group II recites an *in vitro* assay that detects activated glucocorticoid receptors. Group III recites treatment of human patients undergoing glucocorticoid therapy and the assessment of glucocorticoid receptor activation *in vivo* by a method that involves removal of cells or tissue from the patient. Group IV recites screening of molecules of previously unknown nature, and Groups V recites the isolation of an agonist. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups II, III, IV, and V are patentably distinct.

7. Furthermore, the distinct steps and products require separate and distinct searches. Groups II, III, IV, and V each have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any two of Groups II, III, IV, and V together.
8. Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of Invention VI, a glucocorticoid agonist, could be made by processes other than the isolation processes of invention V.

Searching the inventions of Groups V and VI together would impose serious search burden. The inventions of Groups V and VI have a separate status in the art as shown by their different classifications.

9. The inventions of Group VI and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Invention VI, a glucocorticoid agonist, could be used in processes other than the screening process of invention IV. Furthermore, searching the inventions of Groups IV and VI together would impose serious search burden. The search for potential uses for a glucocorticoid agonist would not be coextensive with the search for screening methods. The inventions of Groups IV and VI have a separate status in the art as shown by their different classifications.
10. The inventions of Groups I and V are unrelated. The product of Group I, an antibody molecule, is not used or otherwise involved in the process of Group V, which is a method of isolating a glucocorticoid agonist.
11. The inventions of Groups I and VI are unrelated because they are each structurally and functionally distinct products and they are not disclosed as capable of use together. The product of Group I is an antibody molecule that is used to detect phosphorylations that are correlated with receptor activation. As such it detects activated receptors and does not cause receptor activation. Indeed it binds to the

glucocorticoid receptor at a site distinct from the domain where activating ligands are known to bind. The claimed product of Group VI is functionally defined as a ligand that activates the glucocorticoid receptor. While its structure is undefined, this functional definition would encompass small molecules similar to known glucocorticoids (i.e. not antibodies or proteins) that interact with the known ligand binding domain leading to receptor activation.

12. The inventions of Group VI and Groups II and III are unrelated because the product of Group VI is not used or otherwise involved in the processes of groups II or III.
13. The invention of Group VII and the inventions of Groups II-V are unrelated because the product of Group VII is not used or otherwise involved in the processes of groups II-V.
14. The inventions of Groups VI and VII are unrelated because they are each structurally and functionally distinct products and they are not disclosed as capable of use together. The claimed product of Group VI is functionally defined as an activator of glucocorticoid receptors; its structure would include small molecules similar to known glucocorticoids that are not antibodies or proteins. In contrast, the product of Group VII is, at least, the antigen binding portion of an antibody.
15. Sections 11-14 above each provide rationale for sets of inventions being unrelated and therefore patentably distinct. Furthermore, in each case the recited inventions have a separate status in the art as shown by their different classifications, and the searches required for each invention would not be coextensive with the searches for

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any other invention. Therefore a substantial search burden would be imposed if the inventions were examined together and restriction is deemed proper.

16. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

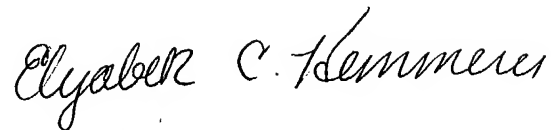
- i. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
- ii. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

- iii. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, PhD, whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

- i. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
- ii. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DCG
Art Unit 1647
28 October 2004



ELIZABETH KEMMERER
PRIMARY EXAMINER